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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/759,749	01/12/2001	Vladimir Puskaric	1326	4891

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EXAMINER

MEHTA, ASHWIN D

ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 01/13/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/759,749	PUSKARIC, VLADIMIR	
	Examiner	Art Unit	
	Ashwin Mehta	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 October 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-44 and 47-49* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1,2,4,6-8,21,23 and 25-27* is/are allowed.

6)☒ Claim(s) *3, 5, 9-20, 22, 24, 28-44, and 47-49* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledg

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. The objection to claims 8 and 27 is withdrawn in light of the claim amendments.

3. The rejection of claims 1-49 under the judicially created doctrine of obviousness-type double patenting is withdrawn in light of the claim amendments.

4. The rejection of claims 1-49 under 35 U.S.C. 112, 2nd paragraph, is withdrawn in light of the claim amendments.

5. The rejection of claims 1-49 under 35 U.S.C. 112, 1st paragraph, requiring a deposit of the seed of plant PH7 JD, is withdrawn, in light of the deposit.

Claim Rejections - 35 USC § 112

6. Claims 3, 5, 12, 13, 22, 24, 30-33, 40-44, and 47-49 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 3 and 22: the recitation "wherein said plant has been manipulated to be male sterile" renders the claim indefinite. It is not clear if the claim is directed towards detasseled

plants, or plants that have been transformed with a gene conferring male steriiity. The following amendments are suggested: 1) in claims 3 and 22, replace "manipulated to be male sterile" with --detasseled--; 2) add a new claim 50 directed towards a method of producing a transgenic male sterile maize plant comprising transforming the maize plant of claim 2 or 21 with a transgene that confers male sterility, and a new claim 51 directed towards a transgenic male-sterile maize plant produced by the method of claim 50.

In claims 5 and 24: there is improper antecedent basis for "protoplasts" in line 1. It is suggested that the term be removed from the claims, and that a new claim be introduced directed towards protoplasts produced from the tissue culture of cells of claim 4 or 23.

In claims 12, 31, and 40: the claim is indefinite because the recitation "comprising" in line 1 does not clearly indicate how many crosses are to be performed by the method. It is suggested that the recitation -- F1-- be inserted into line 1 of claims 12 and 31 after "producing a", and --F1 hybrid-- be inserted in claim 40, lines 1 and 6, before "maize".

In claims 30 and 47: the recitation "essentially unchanged" renders the claims indefinite. It is not clear what is meant by this recitation. If the maize plant of claim 21, for example, [illegible] then it is changed. It is not clear what is meant by the term "essentially."

In claim 33: it is not clear what is meant by a pedigree being within 2 or less crosses to a plant other than PH5TG. There is also insufficient antecedent basis for the recitation "the pedigree".

7. Claims 9-14, 17-20, 28-33, 36-39, 41-44, and 47-49 remain and claims 15, 16, 34, 35, and 40 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record stated in the Office action mailed 05 August 2002 under item 5. Applicants traverse the rejection in the paper filed 28 October 2002. Applicants' arguments have been fully considered but were not found fully persuasive.

Applicants argue that the amendments to claims 3 and 22 obviate the rejection (response, paragraph bridging pages 12-13). The amendments do overcome the rejection, and the rejection has been withdrawn from claims 3 and 22.

Applicants argue that because of the linked genes fixed in PH5TG, one can cross PH5TG with another line, select a plant expressing at least 2 PH5TG traits and a trait from the other plant line (response, page 13, 2nd full paragraph). However, the other parent could also express the some of the same traits as PH5TG and pass it on to the progeny. Further, the traits inherited from the other parent are not known, since the description of the other parent is not provided.

Applicants argue that the fact that technical tools to fully describe the unique characteristics of the full genome of PH5TG do not exist does not make [illegible] derived from them any less entitled to adequate patent protection. Applicants continue, indicating that if the Office now views traits as an unacceptable means of description, other means of description by those of ordinary skill in the art may be used to satisfy written description. Applicants draw analogy to *Ex Parte Tanksley*, in which the Board held that the manner in which Applicants describe their invention is at their discretion (response, paragraph

bridging pages 14-15 and page 15, 1st full paragraph). Applicants continue, arguing that amended claims 17, 33, and 36 limit the progeny covered to those within two outcrosses from PH5TG, and to those of ordinary skill in the art, this indicates that a line that is fewer crosses away from a starting line will be, as a whole, more highly related to the starting line, and the work of the original breeder in developing the starting line will be retained in the closely related progeny (response, page 15, 2nd full paragraph). However, the progeny will also retain the material inherited from the other plants involved in the crosses, which are not described by the specification. The progeny plants would be closely related to the other parent as well.

Regarding Applicants' comment about the acceptance of traits by the Office to satisfy written description: Applicants are requiring the claimed progeny of the deposited line to express only two traits that also expressed by PH5TG. Clearly, plants express many more traits than just two. The traits enumerated in the claims are also not unique to PH5TG, and therefore describing a plant by saying that it expresses 2 particular traits does not distinguish it from any other plant that expresses the same traits. Further, only claim 14 requires the plant to express 2 traits from a Markush listing. The other claims place no limitations on the traits that can be expressed, and can include undescribed traits that are not expressed by PH5TG. Further, claims 17, 33, and 36 do not limit the progeny to be within 2 outcrosses of PH5TG. The term "comprising" leaves the steps involved in the method open. Further, the method can comprise 2 or less outcrosses to any plant that has PH5TG as a progenitor. A plant that has PH5TG as a progenitor does not necessarily have PH5TG as one of its two immediate parents.

Applicants also argue that the mere fact that progeny are not created fails to preclude their patentability, and possession can be shown by describing distinguishing identifying

characteristics (response, paragraph bridging pages 15-16). However, only one of the claims indicates that only 2 of the listed traits need to be expressed, and those listed traits are expressed by other plants. The presence of the traits themselves does not distinguish the claimed plants from other plants that express them, nor do they provide any information of all the other traits of the claimed plants. Applicants argue that pedigree is a distinguishing characteristic that is in compliance with written description guidelines (response, paragraph bridging pages 15-16). However, a pedigree does not describe the morphological and physiological traits of an organism, especially when all of the ancestors of an organism are not described. Further, it is not clear how a plant that is twenty generations removed from PH5TG is described by it. Applicant argues that the genetics of PH5TG is described by the ATCC deposit of its seed, and by limiting the progeny to 2 or less outcrosses, the concern that the progeny are only distantly related to PH5TG is addressed (response, page 16, 1st full paragraph). However, the deposit only describes PH5TG. It does not describe the morphological and physiological traits of any other plant. Further, the claimed plants are not all limited to 2 or less outcrosses.

Applicants argue that one of ordinary skill would know if PH5TG were utilized in a [illegible] program by looking at the breeding records, and that routine molecular techniques can be used to verify whether PH5TG is within the pedigree of a line (response, page [illegible] paragraph). However, determination that PH5TG is an ancestor of a plant does not provide sufficient description of all of the morphological and physiological traits of that plant. Further, the specification does not describe any molecular determinants that one would need to identify any genetic material as having been derived from PH5TG. No description has been provided concerning molecular markers that are unique to the PH5TG genome, for example. Further,

Applicants believe that the tools to fully describe the unique characteristics of the full genome of PH5TG do not exist.

Applicants emphasize that the influence of PH5TG cannot be removed from progeny that are 2 outcrosses removed from PH5TG, and the claimed progeny cannot be derived without the use of PH5TG as a parent. Applicants believe that this highlights the different perspective regarding claim scope between the Examiner and Applicant. Applicant contends that the Examiner's interpretation of the claims to progeny, as being of great breadth because a large number of plants could fall within its scope, ignores the essential limitation that only a plant developed through the use of PH5TG is within the scope of the claim (response, page 17, 2nd full paragraph). However, the influence of the other ancestors of the claimed progeny plants also cannot be ignored. No description is provided at all as to the other ancestors, or the traits expressed by the progeny that are not expressed by PH5TG. As PH5TG is not the only ancestor of the progeny plants, the progeny necessarily express traits that are not expressed by PH5TG. Yet, no description is provided at all concerning those traits. Applicants argue that, to address the Examiner's concern that the PH5TG traits retained by the progeny may be derived from the PH5TG side of the pedigree, claim 14 has been amended to specify that the PH5TG traits were not derived from other plants used in the development of the claimed plant (bridging paragraph bridging pages 17-18). However, again, two traits are not sufficient to describe a plant. The plants of claim 14 express more than just 2 of the traits listed in the claim. Applicant has argued that PH5TG is unique, and that since PH5TG is described, that its descendents must also be described. However, while the combination of genes that produce PH5TG makes that line unique, Applicant does not provide any information as to why the genetic material itself

unique. The claimed plants do not have the complete combination of genes that produce PH5TG. Applicant mentions that claims drawn to plants that contain a unique transgene make it allowable (paragraph bridging pages 14-15). However, Applicants here have not described the qualities of the genetic material of PH5TG that make it unique, other than references to the genctic material as a whole. As the claims are not limited to only self-crosses, all descendents do not inherit all of the genetic material of PH5TG. Descendants also inherit genetic material from other ancestors.

Applicants argue that SSR and RFLP techniques can be used to analyze F1 hybrids and determine if one of its parents is PH5TG, and cite Berry et al. for discussing the probability of identifying the parents of a hybrid by SSR data when neither parent is known (response, page 18, 1st full paragraph). However, choices of possible parents were provided. Further, Applicants have not described any SSR, RFLP, or any other molecular markers that are unique to PH5TG. Applicants also note that a claim to the F1 hybrid made with a deposited line was expressly acknowledged by the United States Supreme Court In *J.E.M. Ag. Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc., USPQ 2d 1865, 1873 (S.Ct. 2001)* (response, page 18, 2nd full paragraph). However,

Applicants also argue, regarding claims drawn towards the deposited lines comprising one or more transgenes or single gene conversions, that examples of traits and single gene conversions are given in the specification. Applicants argue that even if more than one trait is affected by the transgene, that the genetics of PH5TG is only minimally affected, and argue that insertion of one or a few genes into a genome that is estimated to have over 50,000 to 80,000 genes is a minor change (response, page 19, 1st full paragraph). However, Applicants are not

considering the effect of the transgene on the morphological and physiological traits of PH5TG. Even the novice in the art would recognize that even a single gene could potentially have a significant effect on a plant. That the addition a few more nucleotide sequences to the genome of PH5TG fails to significantly add to the total number of nucleotides, is not the point. The transgenes may be of any gene, including those that affect more than one trait. The morphological and physiological characteristics of any such plant are not described. For example, a transgene that is a transcription factor can effect more than just one gene, and multiple traits. Such plants would express different morphological and physiological traits from PH5TG, which are not described. It is suggested that claims 11 and 30 be amended to list the types of transgenes contemplated in the specification, for example disease or pest resistance genes, provided the prior art teaches those isolated genes.

Applicants also argue, regarding the method claims, that the methods are fully described (page 19, last paragraph). However, the progeny plants of PH5TG that are required in the methods are not described, and those plants are a part of the claimed methods.

8. Claims 18-20 and 47-49 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are broadly drawn towards maize plant PH5TG or a maize plant having all the morphological and physiological characteristics of PH5TG, further comprising one or more single gene conversions.

The specification teaches that single gene conversions, or introgression, of the disclosed maize plant through traditional breeding is contemplated (page 21, lines 16-31). However, the specification does not teach any PH5TG plants comprising single gene conversions. It is not clear that single genes may be introgressed into the genetic background of a plant through traditional breeding. Hunsperger et al. (US Patent No. 5,523, 520), Kraft et al. (Theor. Appl. Genet., 2000, Vol. 101, pages 323-326), and Eshed et al. (Genetics, 1996, Vol. 143, pages 1807-1817), for example, teach that it is unpredictable whether the gene or genes responsible for conferring a phenotype in one plant genotypic background may be introgressed into the genetic background of a different plant, to confer a desired phenotype in said different plant. Hunsperger et al. teach that the introgression of a gene in one genetic background in any plant of the same species, as performed by sexual hybridization, is unpredictable in producing a single gene conversion plant with a desired trait (column 3, lines 26-46). Kraft et al. teach that linkage disequilibrium effects and linkage drag prevent the making of plants comprising a single gene conversion, and that such effects are unpredictably genotype specific and loci-dependent in nature (page 323, column 1, lines 7-15). Kraft et al. teach that linkage disequilibrium is created in breeding materials when several lines become fixed for a given set of alleles at a number of different loci, and that very little is known about the plant breeding materials, and ... an unpredictable effect in plant breeding (page 323, column 1, lines 7-15). Eshed et al. teach that in plants, epistatic genetic interactions from the various genetic components comprising contributions from different genomes may affect quantitative traits in a genetically complex and less than additive fashion (page 1815, column 1, line 1 to page 1816, column 1, line 1). In the

absence of further guidance, undue experimentation would be required by one skilled in the art to overcome the difficulties and unpredictability of single gene conversions taught in the prior art.

Claim Rejections - 35 USC § 102 & 103

9. Claims 13, 17, 32, 33, 36, 41, and 43 remain rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Luedtke, Jr. (U.S. Patent No. 6,153,817), for the reasons of record stated in the Office action mailed 05 August 2002 under item 7. Applicants traverss the rejection in the paper received 28 October 2002. Applicants' arguments and the claim amendments were fully considered but were not found persuasive for claims 13, 17, 32, 33, 36, and 41.

Applicants argue that claims 17 and 36 have been limited to a plant two crosses away from PH5TG, and that if an independent claim is non-obvious, any claim depending therefrom must be non-obvious (response, page 21, 3rd full paragraph). However, claims 17 and 36 are product-by-process claims, which may be properly rejected over prior art teaching the same product produced by a different process. See In re Thorpe, 227 USPQ 964,966 (Fed. Cir. 1985). [illegible] can have any number of crosses with plants that do not have PH5TG as a progenitor. Also, the open term "comprises" indicates other steps can be included.

Applicants argue that the plants of claims 41 and 43 are one-cross removed from PH5TG (response, paragraph spanning pages 21-22). However, parent claim 40 does not clearly indicate that the method is only for producing F1 generation plants. It is suggested that claim 40 be amended as discussed above.

10. Claims 1, 2, 4, 6-8, 21, 23, and 25-27 are allowed. Claims 3, 5, 9-20, 22, 24, 28-44, and 47-49 remain rejected.

Contact Information

Any inquiry concerning this or earlier communications from the examiner should be directed to Ashwin Mehta, whose telephone number is 703-306-4540. The examiner can normally be reached on Mondays-Thursdays and alternate Fridays from 8:00 A.M to 5:30 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at 703-306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 and 703-872-9306 for regular communications and 703-872-9307 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

ASHWIN D. MEHTA, PH.D
PATENT EXAMINER

January 7, 2003